

Remarks

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Thus, claim 1 has been amended to limit the definitions for R_1 and R_2 in accordance with claim 2; and also to limit the definition for R in accordance with claim 3.

As a result of these amendments to claim 1, claims 2, 3 and 5 have been cancelled.

Claims 8 and 9 have been cancelled in view of the rejections of these claims under the second paragraph of 35 U.S.C. §112, and 35 U.S.C. §101, rendering these rejections moot.

Claims 10, 11 and 13 have been cancelled in view of the cancellation of claims 2, 3 and 5.

New claims 15-18 have been added to the application.

New claim 15 corresponds to claim 8, but has been drafted in more conventional method of use format according to U.S. practice.

New claims 16-18 correspond to claims 6, 14 and 15, respectively, except that these new claims are dependent on claim 4.

The rejection of claims 1-14 under the second paragraph of 35 U.S.C. §112 based on the term "carbocyclic" has been rendered moot in view of the claim amendments.

The rejection of claims 1-5, 7 and 10-13 under the first paragraph of 35 U.S.C. §112, as applied to the claims remaining after entry of the foregoing amendments, is respectfully traversed.

Applicants take the position that the specification is enabling with regard to the scope of the amended claims. That is, one reasonably skilled in the art could make and use the claimed invention, based on the disclosure in the specification coupled with information known in the art, without undue experimentation. The specification provides examples of starting materials which can be employed in producing the claimed compounds, and also discloses how to produce the claimed compounds from those starting materials. Given this knowledge, one of ordinary skill in the art would be able to prepare other claimed compounds using the same or similar techniques.

Thus, the specification provides considerable direction and guidance to enable the art-skilled to produce the claimed compounds without undue experimentation.

For these reasons, Applicants take the position that the rejection of the claims under the first paragraph of 35 U.S.C. §112 should be withdrawn.

The rejection of claims 6-14 under the first paragraph of 35 U.S.C. §112 is respectfully traversed.

The Examiner takes the position that there is lack of experimental data to support the presently claimed treatment or prevention of hypertension, etc.

However, Applicants note that the paragraph bridging pages 17 and 18 of the specification states that "The compounds of the present invention exhibit inhibiting actions in the in vitro systems at minimum concentrations of about 10^{-6} to about 10^{-10} mol/l." Furthermore, attention is directed to the attached "Test Report", supporting this statement in the specification. The Test Report gives activity data for Examples 3, 7 and 19 in the specification, showing that these Examples exhibit inhibiting action within the disclosed range. The IC_{50} values are given in nMol, that is 10^{-9} Mol.

In view of these considerations, Applicants take the position that one of ordinary skill in the art would be able to use the claimed compounds for the recited purposes, and therefore, the rejection of claims 6-14 under the first paragraph of 35 U.S.C. §112 should be withdrawn.

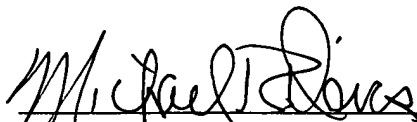
The Examiner provisionally rejects claims 8-9 on the ground of obviousness-type double patenting as being unpatentable over claims 1-2 of Serial No. 11/488,858. Insofar as this rejection is applied against the current method of use claims as set forth above, the Examiner is kindly requested to hold the rejection in abeyance, pending an indication that the claims of the present application are otherwise in condition for allowance.

In view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

Peter HEROLD et al.

By:

A handwritten signature in black ink, appearing to read "Michael R. Davis", written over a horizontal line.

Michael R. Davis

Registration No. 25,134

Attorney for Applicants

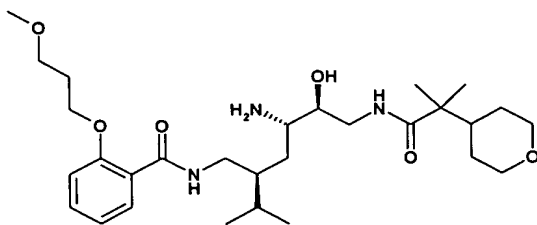
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April 27, 2009

Test Report

General description (see also pages 17/18 of the description)

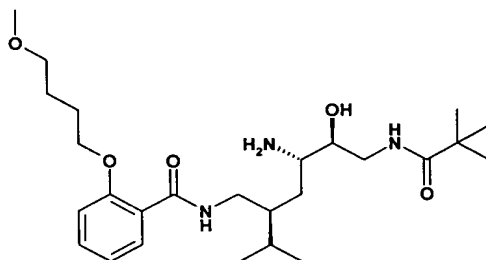
The action of renin inhibitors is detected experimentally with an in vitro test [Nussberger et al. (1987) J. Cardiovascular Pharmacol., Vol. 9, p. 39-44]. This test measures the formation of angiotensin I in human plasma. The amount of angiotensin I formed is determined in a subsequent radioimmunoassay. Which action inhibitors have on the formation of angiotensin I is tested in this system by the addition of different concentrations of these substances. The IC_{50} refers to that concentration of the particular inhibitor which reduces the formation of angiotensin I by 50%. The compounds of the present invention exhibit inhibiting actions in the in vitro systems at minimum concentrations of about 10^{-6} to about 10^{-10} mol/l.

Example 3: N-{4(S)-Amino-5(S)-hydroxy-2(S)-isopropyl-6-[2-methyl-2-(tetrahydropyran-4-yl)-propionylamino]hexyl}-2-(3-methoxypropoxy)benzamide hydrochloride



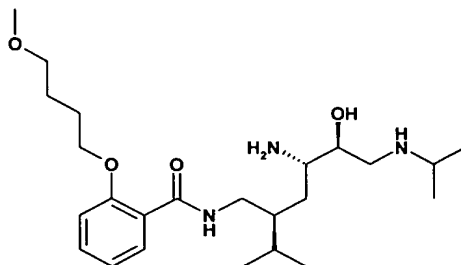
IC_{50} (nM) = 39.3

Example 7: N-[4(S)-amino-6-(2,2-dimethylpropionylamino)-5(S)-hydroxy-2(S)-isopropylhexyl]-2-(4-methoxybutoxy)benzamide hydrochloride



IC_{50} (nM) = 240.0

Example 19: N-(4(S)-amino-5(S)-hydroxy-2(S)-isopropyl-6-isopropylaminohexyl)-2-(4-methoxy-butoxy)benzamide dihydrochloride



IC_{50} (nM) = 317.0